BASIS FOR THE AMENDMENT

Claims 10-14, 16-19, and 25 have been cancelled.

Claim 15 has been amended.

Claims 26-33 have been added.

The amendment of Claim 15 is supported by Claim 15 as originally filed. New Claims 26-33 are supported by Claims 10-14, 16-19, and 25 as originally filed.

No new matter is believed to have been added by these amendments.

REMARKS

Claims 1-9, 15, 20-24, and 26-33 are pending in the present application.

Applicants would like to thank Examiner Haddad and Examiner Chan for the helpful and courteous discussions with their undersigned Representative on June 18, 2002 and July 25, 2002.

The rejections of Claims 10, 12, 14, 16-18, and 25 under 35 U.S.C. §102 over Perlaza et al and of Claims 10-11, 13, and 19 under 35 U.S.C. §103 over Perlaza et al in view of Becker et al are traversed.

The present invention provides a composition *consisting essentially of* a lipopeptide having a sequence of SEQ ID NO: 2 (Claim 26) or SEQ ID NO: 3 (Claim 30), without adjuvant, capable of inducing a mucosal protection in vivo against a malaria infection. In contrast, Perlaza et al disclose the subcutaneous administration of a "*mixture* of peptides as described in Table 1" (page 3423).

In the case of SEQ ID NO: 2, the *Aotus* monkeys were immunized with a *mixture* of LSA3 peptides comprising LSA3-NRI, LSA3-NRII/Lipo (SEQ ID NO: 2), LSA3-RE, and LSA3-CT1/Lipo (see Table 1, page 3424) to elicit an immune response. Similarly, according

to the disclosure of Perlaza et al, SEQ ID NO: 3 must be administered in a *mixture* of LSA1 peptides to elicit an immune response, where the mixture comprises LSA1-J/Lipo (SEQ ID NO: 3), LSA1-NR, LSA1-REP, and LSA1-TER (see Table 1, page 3424). Perlaza et al further disclose that the administration of the LSA3 and LSA1 mixtures led to a strong antibody response for LSA3-NRI, LSA3-NRII, LSA3-RE, LSA1-NR, and LSA1-TER (page 3424, first column). Therefore, based on the disclosure of Perlaza et al it would be obvious that antigen mixtures were required to elicit the aforementioned immune response, and in so doing the mixture would clearly materially affect or alter the basic and novel characteristics of the claimed invention.

Moreover, Perlaza et al do not disclose or suggest that either SEQ ID NO: 2 or SEQ ID NO: 3 are capable of inducing a mucosal protection in vivo against a malaria infection, absent the additional LSA3 or LSA1 peptides, respectively. Even further, at no point do Perlaza et al disclose or suggest a composition consisting essentially of either SEQ ID NO: 2 or SEQ ID NO: 3 without adjuvant. In order for a reference to anticipate an invention, the reference "must teach every element of the claim" (MPEP §2131). Accordingly, Perlaza et al does not anticipate the present invention.

In making an obviousness rejection, the Examiner further cites Becker et al as providing "an immunological composition containing an adjuvant, wherein the lipoprotein is antigenic" (paper number 13, page 8, paragraph 13). However, the presently claimed invention is in the absence of an adjuvant. Moreover, this reference fails to compensate for the aforementioned deficiencies in the disclosure of Perlaza et al.

For the foregoing reasons, Applicants submit that the present invention is not anticipated by Perlaza et al or obvious in view of the combined disclosures of Perlaza et al and Becker et al. Accordingly, Applicants respectfully request withdrawal of this ground of

rejection.

The rejection of Claims 10-13, 16-19, and 25 under 35 U.S.C. §112, first paragraph, is obviated by amendment.

Applicants have amended the claims to recite only the SEQ ID NO: 2 and SEQ ID NO: 3, which the Examiner has conceded is fully enabled by the disclosure of the present application. As such, withdrawal of this ground of rejection is respectfully requested.

The rejection of Claims 10-11, 13, 16, 18-19, and 25 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Claims 10-14, 16-19, and 25 have been canceled in favor of new Claims 26-33. Entry of this amendment, without prejudice toward prosecution of the original claims in a subsequent Continuation application is requested. In view of the amendment presented herein, this ground of rejection is believed to be moot and withdrawal of this ground of rejection is requested.

The objection to the specification is obviated in part by amendment and traversed in part.

As evidenced by page 194 from John McMurry's reference text Organic Chemisty, 3rd Edition (attached herewith), "regiospecific" is appropriately spelled.

Applicants request withdrawal of this ground of objection.

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IN THE SPECIFICATION

Please amend the specification as follows:

Please replace the paragraph beginning on page 4, line 21, with the following text:

Figure 2: Mucosal immunization elicits parasite-specific antibody responses. Sera were obtained from C3H/HeJ mice at 2 weeks post-immunization by either nasal or sub-lingual route and assayed [fro] for recognition of (a) *P. falciparum* sporozoites and (B) hepatic schizonts in an [IFI] IFAT assay as described in [*Material and Methods*] the Examples. The data are representative of three independent experiments.

Please replace the paragraph beginning on page 4, line 26, with the following text:

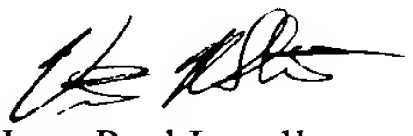
Figure 3: Systemic cellular immune responses are [electited] elicited by presentation of lipid-tailed polypeptides to the nasal and sub-lingual mucosal surfaces. Groups of five C3H/HeJ mice were administrated with LSA3-NRII lipid-tailed (black bars) or non-lipidated polypeptide (hatched bars) either a) intranasally, b) sub-lingually, or c) subcutaneously. Two weeks after two administrations, cell suspensions from individual spleens were assayed for *in vitro* proliferation to the recall polypeptide. Results are expressed as Δ cpm. The background cpm, in unstimulated cells were 1548 [fro] for intranasal, 2356 for sub-lingual and 1965 for subcutaneous routs. Bars represent the mean Δ cpm ± SD in each group. The data were similar and are representative of three separate experiments.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Jean-Paul Lavalleye
Attorney of Record
Registration No. 31,451

Vincent K. Shier, Ph.D.
Registration No. 50,552

22850
(703) 413-3000
Fax #: (703)413-2220
JPL/VKS

IN THE CLAIMS

Cancel Claims 10-14, 16-19, and 25 and insert therefor new Claims 26-33.

Please amend the Claims as follows:

15. (Twice Amended) The method of Claim 9, wherein the lipopetide is:

LSA3-NRII Ac-LEESQVNDDIFNSLVKSVQQEQQHNVK(PAM)NH2 (SEQ ID NO:2) or

LSA1-J Ac-ERRAKEKLQEQQSDLEQRKADTKKK(PAM)NH2 (SEQ ID NO:3).--

--26. – 33. (New)--